

OCT 28 2005

K052713

510(k) Summary of Safety and Effectiveness  
Sechrist Industries, Inc., 3300E/ER Hyperbaric Chamber

## **510 (k) Summary of Safety and Effectiveness**

**Product: Hyperbaric Oxygen Chamber**

**Model: 3300E/ER**

**510(k) No.:**

### General Information

Classification: Class II, CBF  
AN (73), Anesthesiology Panel  
(Title 21, CFR 868.5470)

Trade Name: Chamber, Hyperbaric

Submitter: Sechrist Industries, Inc.  
4225 E. La Palma Ave.  
Anaheim, CA 92807

Contact: Greg Godfrey  
Vice President, Quality Assurance &  
Regulatory Affairs

### Performance Standards:

A performance standard regulation under Section 514 of the Food, Drug and Cosmetic Act has not been promulgated for this device type.

However, the device is designed and manufactured in accordance with the following industry standards:

Section VIII, Division 1 of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code

ASME PVHO-1 Pressure Vessels for Human Occupancy Standard

NFPA 99 Safety Standard for Health Care Facilities, Chapter 20

The following quality assurance measures were applied to the development of the 3300E/ER Hyperbaric Chamber - Requirements specification reviews, performance testing and validation, environmental testing, electrical safety/EMC testing,

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manufacturing process control procedures, process validation, and design change controls.

Substantially Equivalent Devices

<u>Manufacturer</u>	<u>Product</u>
Sechrist Industries, Inc. Anaheim, CA	Model 3200P/PR K950386

Intended Use

The intended use of the Sechrist Model 3300E/ER Hyperbaric Chamber is to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure.

Specific indications for use of hyperbaric chambers have been established by the Committee on Hyperbaric Oxygen Therapy of the Undersea and Hyperbaric Medical Society.

The current specific thirteen indications are:

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and Smoke Inhalation, Carbon Monoxide Complicated by Cyanide Poisoning
3. Clostridial Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhancement of Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections (Subcutaneous Tissue, Muscle, Fascia)
10. Osteomyelitis (Refractory)
11. Radiation Tissue Damage (Osteoradionecrosis)
12. Skin Grafts and Flaps (Compromised)
13. Thermal Burns

Device Description

The Model 3300E/ER Hyperbaric Chamber is a monoplace (one patient) pressure chamber designed to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure.

The Model 3300E/ER Hyperbaric Chamber is constructed with a horizontal seamless acrylic inner cylinder. One end is equipped with a hard anodized aluminum cover and the other with a hard anodized aluminum door assembly, with access ports available for patient support (such as patient monitoring and delivery of intravenous fluids). The control system is pneumatic/electronic containing the controls, indicators, chamber pressure display gauges, and intercom assembly.

Summary of Substantial Equivalence

The design features and materials used in the manufacture of the Sechrist Industries, Inc. 3300E/ER Hyperbaric Chamber are substantially equivalent several pre-amendment products. Additionally the 3300E Hyperbaric Chamber is of similar shape and functionality to the predicate device.

Therefore, due to the similarity of design features, materials, test results and the similarity of the indicated use to other pre-amendment devices and the predicate device+, Sechrist Industries, Inc. believes this product does not have any safety or efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 28 2005

Mr. Greg P. Godfrey  
Vice President, Quality Assurance  
& Regulatory Affairs  
Sechrist Industries, Incorporated  
4225 East La Palma Avenue  
Anaheim, California 92807

Re: K052713

Trade/Device Name: MODEL 3300E/ER MONOPLACE HYPERBARIC OXYGEN  
CHAMBER  
Regulation Number: 21 CFR 868.5470  
Regulation Name: Hyperbaric chamber  
Regulatory Class: II  
Product Code: CBF  
Dated: September 28, 2005  
Received: September 30, 2005

Dear Mr. Godfrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

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Additional Documents 10-27-0

510(k) Number (if known): **K052713**

Device Name: Sechrist Model 3300E/ER Hyperbaric Chamber

### Indications For Use:

The intended use of the Sechrist Model 3300E/ER Hyperbaric Chamber is to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure.

Specific indications for use of hyperbaric chambers have been established by the Committee on Hyperbaric Oxygen Therapy of the Undersea and Hyperbaric Medical Society (founded in 1967 to foster exchange of data on the physiology and medicine of commercial and military diving). The committee is comprised of practitioners and scientific investigators in the fields of internal medicine, infectious diseases, pharmacology, emergency medicine, general surgery, orthopedic surgery, trauma surgery, thoracic surgery, otolaryngology, oral and maxillofacial surgery and aerospace medicine. The committee is responsible for continually reviewing research and clinical data in determining the safety and efficacy of hyperbaric oxygen.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Chris [Signature]*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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## Indications for Use

510(k) Number (if known): **K052713**

Device Name: Sechrist Model 3300E/ER Hyperbaric Chamber

Indications For Use: Currently, there are thirteen indications that are approved by the committee; these thirteen indications were accepted based on sound physiologic rationale, in vivo or in vitro studies that demonstrate effectiveness, controlled animal studies, prospective controlled clinical studies and extensive clinical experience from multiple hyperbaric medicine centers. These thirteen indications have been recommended for third-party reimbursement and most insurance carriers have established reimbursement policy based on these recommendations.

The thirteen indications are:

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and Smoke Inhalation, Carbon Monoxide Complicated by Cyanide Poisoning
3. Clostridial Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness

Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Dr. C. S. John-Of)  
Associate, Anesthesiology, General Hospital,  
Associate, Control, Dental Devices

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Additional Documents 10-27-01

## Indications for Use

510(k) Number (if known): K052713

Device Name: Sechrist Model 3300E/ER Hyperbaric Chamber

#### Indications For Use:

6. Enhancement of Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections (Subcutaneous Tissue, Muscle, Fascia)
10. Osteomyelitis (Refractory)
11. Radiation Tissue Damage (Osteoradionecrosis)
12. Skin Grafts and Flaps (Compromised)
13. Thermal Burns

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

## Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*John C.*

(Mission Sign-Off)  
Division of Anesthesiology, General Hospital,  
Institute of Control, Dental Devices

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